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| 10/552,028 | 10/02/2005 | Nicolas De Roux | CABH.P0006 | 6884 |

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| EXAMINER | |
|---|---|
| ALLEN, MARIANNE P | |
| **ART UNIT** | **PAPER NUMBER** |
| 1647 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/552,028 | DE ROUX ET AL. | |
| | Examiner | Art Unit | |
| | Marianne P. Allen | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *29-52* is/are pending in the application.

4a) Of the above claim(s) *32-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *29-52* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's arguments filed 5/7/07 have been fully considered but they are not persuasive.

Claims 40-52 have been newly introduced.

The rejection of claims 36-39 under 35 U.S.C. 102(e) as being anticipated by Suenaga et al. (U.S. Patent No. 6,838,259) is obviated by amendment of the claims.

### *Election/Restrictions*

Newly submitted claims 40-52 and claims 32-39 as amended are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 32-52 are directed to methods and not compositions. The originally claimed compositions lack a special technical feature as prior art has been applied against these claims. As such, there is no unity of invention among the compositions and methods.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-52 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 29-31 are under consideration by the examiner.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 29-31 are not originally filed claims. They were added in the preliminary amendment filed 10/2/05 and amended on 5/7/07. Applicant now points to basis on page 5, lines 33-38 and at pages 17-18. No basis for the claimed invention is seen. It is noted that the specification does not have a page 18 and page 5 describes Figure 5. Figure 5 presents results from a particular experiment and does not disclose the general concept set forth in claims 29-31. Page 17 discloses compositions comprising GnRH and suitable agonists or antagonists of GPR54, where suitable ratios of GnRH to the agonist/antagonist range between 10:1 to 1000:1 in Molar concentration. Original claims 26-28 (now cancelled) were directed to compositions comprising GnRH and the agonist or antagonist of claim 5 or any one of the claims 21 to 25. Particularly disclosed is a composition according to claim 26, wherein the agonist is the fragment 45-54 of Kiss-l. (Claim 5 and 21-25 are also now cancelled.) The present claims do not reflect these concepts and no basis is seen for the claims. The specification does not suggest a composition comprising GnRH and at least one of Kiss-1 peptides, Kiss-1 peptide fragments, kisspeptins, a salt of Kiss-1 peptides, a salt of Kiss-1 peptide fragments, and a salt of kisspeptins. There is no disclosure of **more than one** component with GnRH. Only the fragment 45-54 of Kiss-1 is disclosed as being an agonist. No other Kiss-1 peptides, Kiss-1 peptide fragments, kisspeptins, salt of Kiss-1 peptides, salt of Kiss-1 peptide fragments, and salt of kisspeptins embraced by the claims is disclosed as being or is required to be an agonist or antagonist of GPR54.

Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

This rejection is maintained for reasons of record.

Applicant argues that Kiss-1 peptide, fragment 45-54 of Kiss-1, Kiss-1 peptide fragments, kisspeptins, or salts thereof would have been well known proteins and as such the specification need not disclose the structures of these proteins. Applicant further argues that the compounds in the claims have a defined meaning in the art. Applicant has provided no evidence in support of these assertions. Applicant has not provided any references or evidence establishing that the structures of the recited proteins would have been well known or that the compounds referenced in the claims have a defined meaning in the art. While applicant mentions Katani et al. and Otaki et al., these references are not of record. While applicant argues that WO-A-2003003983 and EP-A-1126028 disclose the full sequence of the claimed proteins, the examiner did not locate this disclosure and applicant did not point out particularly where in these references this information was located. Secondly, the full length protein of a single protein does not define or inform one of ordinary skill in the art with the totality of what is being claimed, including the identity of all Kiss-1 peptides embraced by the claims, all fragments, all kisspeptins, and all salts.

Applicant's reliance on Moba v. Diamond Automation, 325 F. 3rd 1306 is misplaced. The portion pointed to is from the concurring opinion by Judge Rader which discusses the Lilly

decision. Moba v. Diamond Automation was an infringement case with respect to methods of advancing and transferring eggs using particular steps and devices. The facts of this case bear no resemblance to the present situation. The commentary by Judge Rader is not germane to the instant application. It outlines his belief that by making written description a free-standing disclosure doctrine, the court produces numerous unintended and deleterious consequences. The concurring opinion by Judge Bryson does not agree with Judge Rader's view of Lilly.

Again, with the exception of fragment 45-54 of Kiss-1 as discussed on page 17, the specification does not disclose any activity for these proteins in combination with GnRH. The specification does not disclose any other fragments of Kiss-1 that would have activity, particularly in combination with GnRH.

Figure 5 and page 17 disclose using the combination of fragment 45-54 of Kiss-1 and GnRH in an in vitro perifusion assay of rat pituitary tissue. The 45-54 fragment of Kiss-1 at $10^{-8}$ M and GnRH at $10^{-6}$ M shows modulation of the GnRH effect on LH synthesis. This combination extends the effect of GnRH on LH stimulation by the pituitary. However, other concentrations or ratios of Kiss-1 or GnRH are not tested and it cannot be predicted that other Kiss-1 or kisspeptin peptides or other amounts of these peptides with other amounts of GnRH would have any activity.

The specification does not disclose how to use all compositions embraced by the claims, particularly those for which no biological activity has been established. Applicant's arguments are not understood. The rejection of record is not a utility rejection. Applicant's arguments do not address the unpredictability of the results. One would not have been able to extrapolate the

results discussed above to predict the results of other embodiments embraced by the claims. Applicant has offered no explanation of why they believe these results could have been extrapolated. No other embodiments appear to have been exemplified.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is confusing in reciting a ratio between 10:1 and 1000:1 molar concentration. It is unclear when there is more than one component with GnRH (e.g. both Kiss-1 peptides and kisspeptins are present with GnRH) whether or not the ratios are with respect to each one (e.g. GnRH to Kiss-1 peptide between 10:1 and 1000:1 and GnRH to kisspeptins is also between 10:1 and 1000:1) or whether the ratio is with respect to GnRH and all of the components in part b) of claim 29 (e.g. GnRH to the combined amounts of Kiss-1 peptide and kisspeptins is between 10:1 and 1000:1).

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 29 and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Seminara et al. (*New England Journal of Medicine*, 23 October 2003).

This rejection is maintained for reasons of record.

Applicant's arguments are unpersuasive. The claims do not indicate that the composition is isolated or purified or that any components are isolated or purified. The use of "comprising" permits inclusion of other components and does not exclude a living organism such as a mouse.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marianne P. Allen 7/3/07
Marianne P. Allen
Primary Examiner
Art Unit 1647

mpa